JUICE PRODUCTS ASSOCIATION

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February 5, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Agency Information Collection Activities: Proposed Collection; Comment Request; Hazard Analysis and Critical Control Point; Procedures for the Safe and Sanitary Processing and Importing of Juice **Docket No. 2003N-0525**

The Juice Products Association (JPA) is a trade association whose international membership consists of major packers and distributors of a wide variety of fruit and vegetable juices, juice beverages, and drinks. Our members represent a significant majority of the juice and juice beverage processors in the United States. JPA submits the following comments on the Food and Drug Administration's (FDA) notice published in the December 8, 2003, *Federal Register* (68 *Federal Register 68400*), regarding the Agency's collection of information pertaining to the recordkeeping requirements mandated in FDA's hazard analysis and critical control point (HACCP) regulations (21 CFR Part 120).

JPA believes the current recordkeeping requirements outlined in 21 CFR Part 120 are sufficient to document a company's efforts in implementing and maintaining a HACCP program.

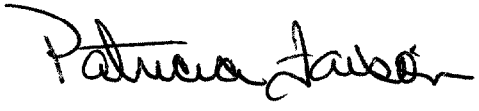
Table 1, Estimated Annual Recordkeeping Burden, estimates that every juice importer will utilize four hours annually to ensure that the recordkeeping requirements outlined in 21 CFR 120.14 ("Application of Requirements to Imported Products") are met. We believe that it will take considerably more than 4 hours annually for importers to ensure they have the appropriate documentation showing that the imported juice has been processed under regulations outlined in 21 CFR 120. Each processor is required to validate that their HACCP plan is adequate to control food hazards that are reasonably likely to occur at least once within 12 months after implementation and at least annually thereafter, according to 21 CFR 120.11 (b). During the annual validation process, it is likely that importers will contact their juice suppliers/processors to ensure that their HACCP records are current. We estimate that this could take approximately 30 – 40 hours per validation depending on the number of suppliers an importer uses.

In addition, FDA estimates that it will take 0.01 hours (0.6 minutes) per record to comply with 21 CFR 120.8(b)(7), which specifies that processors must provide a recordkeeping system that documents the monitoring of the critical control points in accordance with 21 CFR 120.12. These records must contain the actual values and observations obtained during monitoring. While there are on-line electronic recording devices, some monitoring and recording activities may be performed manually (e.g., measuring the chlorine content of a sanitizing solution using a chlorine test kit or testing and recording product fill temperatures). We believe that on average, these activities may take at least 2 – 3 minutes or more depending on the critical control point.

According to 21 CFR 120.11, processors must verify, date and sign: monitoring records, records showing corrective action; records showing the calibration of monitoring instruments used at critical control points and records showing periodic end-product or in-process testing that is part of the processor's verification activities. It appears that FDA estimates this verification activity to occur at least once per week, based on the value of 52 under the heading "Annual Frequency of Recordkeeping." Although, the regulations in 21 CFR 120.11 permit this activity to occur within 1 week (7 days) after the record is created, we believe that many processors are verifying some records on a daily basis.

We appreciate your consideration of these comments.

Sincerely,



Patricia Faison
Technical Manager

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